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Recipient  Examiner Fubara, Group 1618		Company USPTO	Fax 571-273-8300  Number of Pages	<b>Phone</b> 571-272-0594 5
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#### Comments

# ATTORNEY'S DOCKET NUMBER: 0492611-0417 (MIT 8966) IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Kohane et al.

Examiner:

Fubara, Blessing M.

Serial No.:

09/981.020

Art Unit:

1618

Filed:

October 16, 2001

For:

LIPID-PROTEIN-SUGAR PARTICLES FOR DRUG DELIVERY

#### Dear Examiner Fubara:

Attached is a set of amended claims to facilitate our discussion of this application next Tuesday (August 22nd) at 10 am. Please do *not* enter these amendments into the case at this time. We look forward to speaking with you next week.

Sincerely,

C. Hunter Baker, M.D., Ph.D. and Nicole Clouse, Ph.D.

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### Listing of Drafted Claims

- A pharmaceutical composition comprising solid microparticles, wherein the 86. microparticles are not liposomes, comprising:
  - (a) a matrix comprising:
    - (i) dipalmitoyl phosphatidylcholine (DPPC);
    - a sugar selected from the group consisting of galactose, lactose, (ii) glucose, maltose, starches, cellulose and its derivatives, methyl cellulose, carboxymethyl cellulose, fructose, dextran and its derivatives, raffinose, mannitol, xylose, dextrins, glycosaminoglycans, sialic acid, chitosan, hyaluronic acid, and chondroitin sulfate; and
    - (iii) a protein; and
  - **(b)** an agent, wherein the agent is encapsulated in the matrix.
- 87. A pharmaceutical composition comprising solid microparticles, wherein the microparticles are not liposomes, comprising:
  - a matrix comprising: (a)
    - (i) a lipid selected from the groups consisting of phosphoglycerides; phosphatidylcholines; dipalmitoyl phosphatidylcholine (DPPC); dioleylphosphatidyl ethanolamine (DOPE); dioleyloxypropyltriethylammonium (DOTMA); dioleoylphosphatidylcholine; cholesterol; cholesterol ester;

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diacylglycerol; diacylglycerolsuccinate; diphosphatidyl glycerol (DPPG); hexanedecanol; fatty alcohols; polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid; palmitic acid; oleic acid; fatty acids; fatty acid amides; sorbitan trioleate (Span 85) glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester; sorbitan trioleate; lecithin; lysolecithin; phosphatidylserine; phosphatidylinositol; sphingomyelin; phosphatidylethanolamine (cephalin); cardiolipin; phosphatidic acid; cerebrosides; dicetylphosphate; dipalmitoylphosphatidylglycerol; stearylamine; dodecylamine; hexadecyl-amine; acetyl palmitate; glycerol ricinoleate; hexadecyl sterate; isopropyl myristate; tyloxapol; poly(ethylene glycol)5000-phosphatidylethanolamine; and phospholipids;

- (ii) lactose; and
- (iii) a protein; and
- (b) an agent, wherein the agent is encapsulated in the matrix.
- 88. A pharmaceutical composition comprising solid microparticles, wherein the microparticles are not liposomes, comprising:
  - (a) a matrix comprising:
    - (i) a lipid selected from the groups consisting of phosphoglycerides; phosphatidylcholines; dipalmitoyl phosphatidylcholine (DPPC); dioleylphosphatidyl ethanolamine (DOPE); dioleyloxypropyltriethylammonium (DOTMA); dioleoylphosphatidylcholine; cholesterol; cholesterol ester; diacylglycerol; diacylglycerolsuccinate; diphosphatidyl glycerol (DPPG); hexanedecanol; fatty alcohols; polyethylene glycol (PEG); polyoxyethylene-9-lauryl ether; a surface active fatty acid; palmitic acid; oleic acid; fatty acids; fatty acid amides; sorbitan trioleate (Span 85) glycocholate; surfactin; a poloxomer; a sorbitan fatty acid ester; sorbitan trioleate; lecithin; lysolecithin;

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phosphatidylserine; phosphatidylinositol; sphingomyelin; phosphatidylethanolamine (cephalin); cardiolipin; phosphatidic acid; cerebrosides; dicetylphosphate; dipalmitoylphosphatidylglycerol; stearylamine; dodecylamine; hexadecyl-amine; acetyl palmitate; glycerol ricinoleate; hexadecyl sterate; isopropyl myristate; tyloxapol; poly(ethylene glycol)5000-phosphatidylethanolamine; and phospholipids;

- (ii) a sugar selected from the group consisting of galactose, lactose, glucose, maltose, starches, cellulose and its derivatives, methyl cellulose, carboxymethyl cellulose, fructose, dextran and its derivatives, raffinose, mannitol, xylose, dextrins, glycosaminoglycans, sialic acid, chitosan, hyaluronic acid, and chondroitin sulfate; and
- (iii) a protein; and
- (b) an agent, wherein the agent is encapsulated in the matrix.
- 89. The pharmaceutical composition of claim 88, wherein the protein is albumin.
- 90. A pharmaceutical composition comprising solid microparticles, wherein the microparticles are not liposomes, comprising:
  - (a) a matrix comprising:
    - (i) dipalmitoyl phosphatidylcholine (DPPC);
    - (ii) lactose; and
    - (iii) albumin; and
  - (b) an agent, wherein the agent is encapsulated in the matrix.
- 91. The pharmaceutical compositions of any one of claims 86-90, wherein the ratio of lipid to protein to sugar is approximately 3:1:1.
- 92. The pharmaceutical compositions of any one of claims 86-90, wherein the ratio of lipid to protein to sugar to agent is approximately 54:18:10.

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- 93. The pharmaceutical compositions of any one of claims 86-90, wherein the lipid comprises 20-60% of the matrix by weight; wherein the protein comprises 10-30% of the matrix by weight; and wherein the sugar comprises 10-30% of the matrix by weight.
- 94. The pharmaceutical compositions of any one of claims 86-90, wherein the agent is a small molecule.
- 95. The pharmaceutical compositions of any one of claims 86-90, wherein the agent is a protein.
- 96. The pharmaceutical compositions of any one of claims 86-90, wherein the agent is a polynucleotide.